FACT SHEET FOR HEALTHCARE PROVIDERS: INTERPRETING CDC *HUMAN INFLUENZA VIRUS REAL-TIME RT-PCR DETECTION AND CHARACTERIZATION PANEL FOR RESPIRATORY SPECIMENS (NPS, NS, TS, NPS/TS, NA[1]) AND VIRAL CULTURE TEST RESULTS*

May 2, 2009

A public health emergency has been declared by the Secretary of Health and Human Services because of the 2009 outbreak caused by novel influenza A (H1N1) virus. This virus is also referred to as swine influenza (H1N1) virus. This Fact Sheet will refer to the virus as novel influenza A (H1N1). The Food and Drug Administration (FDA) has authorized the emergency use of the CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel for Respiratory Specimens (**NPS, NS, TS, NPS/TS, NA**) and Viral Culture [rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**)] as a first tier test for the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) for individuals suspected of having a novel influenza A (H1N1) infection under an Emergency Use Authorization (EUA). This authorization will terminate on April 26, 2010, when the emergency has ceased to exist, or when the authorization is revoked, whichever is earlier. The information in this Fact Sheet is the minimum necessary to inform you of the significant known and potential risks and benefits of the emergency use of the rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**).

The rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) is authorized for the *in vitro* qualitative detection of influenza types A and B and influenza A H1 (seasonal) and H3 subtypes in nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), and/or dual NPS/TS swab specimens and nasal aspirates (NA) from patients with signs and symptoms of respiratory infection and/or from viral culture.

The rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) should be ordered to diagnose influenza A infections caused by influenza A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) to be used as a first tier test for the *in vitro* qualitative detection of novel influenza A (H1N1) virus in patients suspected of having novel influenza A (H1N1) infection. If the test result is positive for influenza A and negative for seasonal H1 and H3 subtypes, the laboratory should test the specimen with the Swine Influenza Real-time RT-PCR Detection Panel (rRT-PCR Swine Flu Panel) for the presumptive detection of novel influenza A (H1N1) infection. Although this test is authorized for use with nasopharyngeal swabs, nasal swabs, throat swabs, and/or dual NPS/TS swab specimens and nasal aspirates, it is strongly recommended that nasopharyngeal or nasal swabs be collected. The specimens may be collected in the usual fashion and sent to a qualified laboratory for analysis. Specimen collection should be conducted per the clinical protocol and according to the manufacturer's instructions for the specimen collection device.

What does it mean if the specimen tests positive for influenza A and negative for influenza H1 and H3 subtypes using the rRT-PCR Flu Panel (NPS, NS, TS, NPS/TS, NA)?

An rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) test result positive for Influenza A and negative for H1 and H3 subtypes indicates that the patient is presumptively infected with Influenza A virus, but not with seasonal influenza virus subtypes. In the context of the novel influenza A (H1N1) virus outbreak, such test result should be followed by testing with rRT-PCR Swine Flu Panel. Laboratory test results should always be considered in the context of clinical observations and epidemiologic data in making a final diagnosis. For guidelines on managing patients please refer to *"Interim Guidance for Infection Control for Care of Patients with Confirmed or Suspected Swine Influenza A (H1N1) Virus Infection in a Healthcare Setting"* and *"Interim Guidance on Antiviral Recommendations for Patients with Confirmed or Suspected Swine Influenza A (H1N1) Virus Infection and Close Contacts"* at http://www.cdc.gov/h1n1flu/guidance/.

[1] Nasopharyngeal swabs, nasal swabs, throat swabs, dual nasopharyngeal swabs/throat swabs, nasal aspirates.

What does it mean if the specimen tests positive for influenza A and positive for either H1 or H3 subtype using the rRT-PCR Flu Panel (NPS, NS, TS, NPS/TS, NA)?
If the specimen tests positive for influenza A and positive for either H1 or H3 subtype using the rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)**, this result indicates that the individual has been infected with seasonal Influenza A virus. However this result should not be used as the sole basis for treatment or other patient management decisions. The clinical features of the illness and the type and risk of exposure are the keys to making patient management and isolation decisions.

What does it mean if the specimen tests negative for influenza A using the rRT-PCR Flu Panel (NPS, NS, TS, NPS/TS, NA)?
Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. The clinical features of the illness and the type and risk of exposure are the keys to making patient management and isolation decisions. A negative rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) test should not be interpreted as demonstrating that the patient does not have novel H1N1 virus infection, if other aspects of the patient's clinical presentation or recent epidemiologic exposures indicate novel H1N1 virus infection is likely, and diagnostic tests for other causes of acute respiratory illness are negative.

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*****Any significant new findings observed during the course of the emergency use of rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**)will be made available at http://www.cdc.gov/h1n1flu/.